REMARKS

I. Rejections Under 35 U.S.C. §102

In the Final Office Action, the Examiner rejected Claims 1-11, 13-19, and 35-48 as being anticipated by Colone (U.S. Patent No. 7,465,483), which is newly-cited. Applicant respectfully submits that, as amended, these claims patentably distinguish over Colone.

Initially, applicant notes in contrast to the claimed invention, Colone does not teach a catheter balloon. Instead, Colone teaches a porous, sintered, tubular polytetrafluoroethylene (PTFE) material suitable for use in the medical field as liners and covers attached to expandable stents. See Col. 1, lines 20-22 ("the invention relates to extruded, stretched, sintered tubular PTFE materials for use in the medical field as liners and covers for expandable stents"); Col. 3, lines 49-52 ("The resulting stretched, sintered, porous tubes consisted essentially of highly crystalline PTFE polymer and had a microstructure characterized by nodes interconnected by fibrils.").

Porous products such as that present in Colone are generally unsuitable for making high pressure balloons or pressure expandable dilation devices such as those which are the subject matter of the claimed invention. For example, the presence of pinholes in PET balloons is considered detrimental to their utility, rendering such balloons possibly dangerous to the patient. See Paragraph 20 ("For example, PET balloon in particular have been found to be subject to development of pinholes, are fragile and easily damaged during routine handling, and may develop extensive wrinkles when the balloon is sterilized.")

In contrast to the porous material of Colone, and as currently amended, independent Claims 1, 11 and 39 now recite that the polymer utilized in the claimed balloon is "continuous." Support for this amendment may be found in the Specification. See, e.g., Paragraph 30 ("In

accordance with a preferred embodiment of the present invention, a polymer material is first extruded or otherwise formed into a continuous tube of a desired length and outside and inside diameter."); Paragraph 70 ("It should be noted that the "reduced size tubular member with expansion memory" of the present invention, if constructed in the form of a hollow cylinder, may comprise walls which may be continuous, or discontinuous. For example, perforations in the wall with openings or holes of various sizes can be provided.") As shown by this quoted language, the term "continuous" as used in the Specification means a material that lacks "perforations"; i.e., "openings or holes." Thus, a continuous tube as taught in the Specification is non-porous, making it capable of retaining a consistent pressure and thus suitable for use in making a high pressure angioplasty balloon.

Applicant separately asserts the patentability of Claim 5, now rewritten in independent form, and Claim 6, which depends thereon. Claim 5 is directed to a catheter balloon where in the balloon comprises a "crosslinked polymer." As acknowledged by the Examiner in the Final Office Action, the polymer in Colone is "non-crosslinked." Applicant has deleted the language in prior Claim 5 regarding a "polymer with a shrink memory."

Applicant asserts the patentability of independent Claim 11, and Claims 13-19, 36, 38 and 43 that are dependent thereon, based on the "continuous" feature discussed above. In addition, Applicant separately asserts the patentability of these claims based on the feature that the balloon has a wall thickness that is *less than* the wall thickness of the continuous polymer tube from which the balloon is formed. This feature is not shown in Colone. That reference instead teaches a "radially pre-dilated" porous PTFE polymer tube that is radially dilated and then sintered. When the radially dilated tube is sintered the dilated tube is contracted to a configuration in which the inner diameter of the tube substantially equals its original inner

diameter. Col. 10, lines 28-51; see also Col. 14, Tables XIII and XIV (demonstrating that after pre-dilation, the sintered tube also returns to an outer diameter substantially equal to the original tube). Thus, in Colone and in contrast to Claim 11, the wall thickness of the stretched, predilated, sintered tube is the same as tube from which it is formed.

Applicant asserts the patentability of independent Claim 39, and Claims 40-41 and 44 that are dependent thereon, based on the "continuous" feature discussed above.

In conclusion, Applicant respectfully submits that this Amendment, including the amendments to the Claims and in view of the Remarks provided in connection therewith, fully responds to all aspects of the Examiner's rejections tendered in the Final Office Action. Applicants therefore earnestly solicit the issuance of a Notice of Allowance with respect to Claims 1-11, 13-19 and 35-48.

If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the below-listed number.

If there are any additional fees incurred by this Amendment, please deduct them from our Deposit Account No. 23-0830.

Respectfully submitted,

/Jeffrey Weiss/
Jeffrey Weiss
Reg. No. 45,207
(202) 682-1722